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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,071	10/23/2002	Michael E. O'Donnell	22221/1023	1435

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/048,071	O'DONNELL ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-91* is/are pending in the application.

4a) Of the above claim(s) *2-34,40-54 and 58-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,35-39 and 55-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

8-0-0

DETAILED ACTION

Amendment

1. Applicant's response to restriction requirement filed on 1/06/05 is acknowledged.

Election/Restriction

2. Applicant's election of Group VIII, claims 1, 35-39 and 55-57 drawn to isolated dnaN gene, SEQ ID NO: 27 and DNA encoding the amino acid sequence of SEQ.ID.NO: 28 with traverse is acknowledged.

Applicant traverses the restriction and states that the claims of the present invention are closely related and, therefore, require common areas of search and consideration. Since no benefit is derived from imposing this restriction requirement, it should be withdrawn in its entirety.

This is not found persuasive because the application has been filed under 35 U.S.C. 371 and the examiner followed the Lack of Unity practice as per PCT rule 13.1 and 13.2. The examiner as indicated in the previous office action in detail, the groups of inventions are not linked so as to form a single general inventive concept under PCT Rule 13.1. Although the applicant's concept "closely related " may link the groups such concept does not constitute a special technical feature as defined by PCT Rule 13.2 (37CFR1.475(a) because the expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Specifically, Kunst et al 1997, Nature, Vol, 390, 249-256 teach an isolated *Bacillus subtilis (*, a gram positive) genome sequence that includes open reading frames (coding region) from genes polCgene, a dnaE gene, a holA gene, a holB gene, a dnaX gene, a dnaN gene, a ssb gene, a dnaG gene, or a dnaB gene (Table 1, figure 1and III). Further, there is no common structure, function or property (i.e., special technical feature) between the genes. Therefore, it does not constitute a special technical feature by definition. Therefore, unity of invention is lacking.

With respect to common search, there is no claimed common structural requirement that is common to all of the proteins that are described in the claims and the specification as having separate functions. A separate search and examination for each function and structure is required and as such establishes an undue search and examination burden. Further, it is not persuasive, because Applicants have not established a common structure or functional feature held in common between all the polypeptide that would be necessarily establish unity between the polypeptides.

With respect to applicants assertion that no benefit is derived from imposing the restriction requirement, Applicants are reminded that an Applicant gets a single patent for a single invention and are not entitled under 35 U5C S 111 for the examination of multiple independent and distinct inventions in the same patent application. The requirement is still deemed proper and is therefore made FINAL

Applicant timely traversed the restriction (election) requirement in the reply filed on 1/06/05.

Status of claims

3. Claims 1, 35-39 and 55-57 are under examination with respect to SEQ.ID.NO: 27 and 28. Applicant is advised to limit the claim1 to the elected invention dnaN gene.

Claims 2-34, 40-54, 58-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions M.P.E.P § 821.03.

Priority

4. This application is a 371 national stage entry of PCT/US00/20666International Filing Date: 07/28/2000 which claims priority to application U.S. 60/146,178, 07/29/1999.

Information Disclosure Statement

5. The Information Disclosure Statement is not filed in this application.

Specification Informalities

6. Neither the specification nor the brief description of drawings set forth the Sequence identification numbers as listed in the sequence listing.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Applicant is encouraged to update the status of priority documents in the specification and submit a new abstract, as current abstract does not clearly set forth applicant's elected invention.

Claim Rejections - 35 USC 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 35-39 and 55-57 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the revised guidelines on written description available at www.uspto.gov (O.G. published January 30, 2001). This is a written description rejection.

Claims 1 and 35-39 are drawn to an isolated DNA molecule from a Gram positive bacterium, the isolated DNA molecule comprising a coding region from (a polC gene, a dnaE gene, a holA gene, a holB gene, a dnaX gene), a dnaN gene, (a ssb gene, a dnaG gene, a dnaB gene), wherein the DNA molecule comprises the coding region from the dnaN gene, wherein the Gram positive bacterium is *Streptococcus pyogenes, wherein* the DNA molecule encodes an amino acid sequence comprising SEQ. ID. NO. 28, wherein the DNA molecule comprises a nucleotide sequence of SEQ. ID. NO. 27, wherein the DNA molecule hybridizes to a nucleic acid molecule of SEQ. ID. NO. 27 under stringent conditions characterized by use of

hybridization buffer comprising 0.9M SSC buffer at a temperature of 37°C.

Claims 55-57 are drawn to an expression system comprising an expression vector into which is inserted a heterologous DNA molecule comprising a coding region from dnaN gene, wherein the heterologous DNA molecule is in sense orientation and correct reading frame and a host cell comprising said a heterologous DNA molecule.

Recitation of "a nucleic acid " "an amino acid " "a DNA "sequence in the claims are viewed as more than one sequence or less than the full length sequence (i.e., fragments).

The specification describes an isolated DNA sequence from *S.pyogenes* comprising the nucleic acid sequence (1124 nucleic acids) SEQ.ID.NO: 27 and is named as dnaN gene. The specification on page 17 teaches that this gene encodes beta sub unit of DNA polymerase comprising the amino acid sequence, SEQ.ID.NO: 28 having 378 amino acids. However, the function of this gene (i.e., SEQ.ID.NO: 27) or its product (SEQ.ID.NO: 28) in assessing *S.pyogenes* infection or pathogenesis has not yet been identified. The specification fails to disclose the structure of these fragments of SEQ.ID.NO: 27, SEQ.ID.NO: 28 and DNA that hybridizes to a nucleic acid molecule (i.e., fragments). The function of these fragments has not been disclosed. Therefore, said fragments do not meet the guidelines on written description.

The specification fails to disclose any substitution, insertion or deletion or change in a DNA, SEQ.ID.NO: 7 to obtain functional fragments of DNA. The specification does not describe any use of said DNA fragments as claimed (comprising, open language) in identifying Streptococcus pyogenes. None of the above polypeptides meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116).

Thus, the specification fails to teach the above discussed fragments of nucleic acid and thereby does not satisfy the written description guidelines because the claimed isolated nucleic acid or its fragments has not been shown to have any function. In addition, a polypeptide encoded by a nucleic acid comprising (open language) an amino acid sequence SEQ.ID.NO: 28 plus unlimited and unknown nucleic acids, a DNA comprising fragments of SEQ.ID.NO: 27 plus unlimited and unknown nucleic acids and a DNA molecule comprising a DNA that hybridizes to a nucleic acid molecule to a nucleic acid molecule plus unlimited and unknown nucleic acids would result in an unknown isolated DNA without sufficient structure and completely lacking identifying characteristics such as function. Thus, isolated DNA fragments as claimed are broader than the SEQ.ID.NO: 27 or encoding fragments of SEQ.ID.NO: 28 and do not appear to have sufficient structural characterization and lack any identifying characteristics (function). The specification fails to teach the structure or relevant identifying characteristics sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making it. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chugai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. Since there is no support for said fragments, the expression vectors and host cells comprising said fragments also lack written description support.

9. Claims 1, 35-39 and 55-57 are rejected under 35 U.5.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule from *Streptococcus pyogenes* (*S.pyogenes)* consisting of the dnaN coding region, the nucleic acid sequence, SEQ.ID.NO: 27, wherein the molecule is in sense orientation and correct reading frame, an

isolated DNA molecule encoding the amino acid sequence, SEQ. ID. NO: 28, an expression system comprising an expression vector and a host cell comprising said expression vector does not reasonably provide enablement for an isolated DNA molecule from other gram positive bacteria, the isolated DNA molecule comprising a coding region dnaN gene from gram positive bacterium is wherein the DNA molecule encodes an amino acid sequence comprising SEQ. ID. NO: 28, wherein the DNA molecule comprises a nucleotide sequence of SEQ. ID. NO: 27 wherein the DNA molecule hybridizes to a nucleic acid molecule of SEQ. ID. NO: 27 under stringent conditions characterized by use of a hybridization buffer comprising 0.9M SSC buffer at a temperature of 37^{o}C, an expression system comprising an expression vector into which is inserted a heterologous DNA molecule from a Gram positive bacterium and an isolated host cell comprising said expression vectors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims are discussed supra in paragraph # 8

The specification fails to provide an enabling disclosure for the full scope of claimed isolated DNA fragments as discussed above in the written description rejection because it fails to provide any guidance regarding how to make and use said isolated DNA fragments.

The instant claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the disclosed invention is drawn to identifying new genes, involved in bacterial replication from the Gram-positive bacteria *Streptococcus pyogenes* (e.g., S. pyogenes). They are assigned names based on their nearest homology to subunits in *the E. coli* system. The genes encoding *E. coli* replication proteins are alpha (dnaE), epsilon (dnaQ), theta (holE), tau (full length dnaX), gamnma (frame shift product of dnaX), delta (holA), delta prime (holB), chi (holC), psi (holD), beta (dnaN), DnaB helicase (dnaB) and primase (dnaG). The state of the art indicates that there is very little information available in replication mechanisms of Gram-positive organisms, Staphylococcus aureus Streptococcus pneumoniae, and Streptococcus pyogenes. The art indicates that three DNA polymerases I, II and III are involved in gram-negative bacterial replication. However, whether the S. pyogenes three component polymerase can synthesize DNA in as rapid and recessive fashion as the E. coli Pol III holoenzme three component polymerase is very difficult to predict, because no other DNA polymerase known to date catalyzes synthesis at the rate or processivity of the E. coli three component polymerase indicating the unpredictability in the art. Whether the claimed dnaN gene or its product involved in critical cell function, such that blocking its action with a drug causes the pathogenic cell to die or no longer proliferate in a screening assay for the identification of an anti-microbial drug utilizing a peptide encoded by an operon comprising a nucleotide sequence SEQ.ID.NO: 27 *S. pyogenes* is yet to be experimented. The specification on page 13 recite that the three component polymerase can synthesize DNA as rapid and processive fashion as the *E. coli* Pol III holoenzme three component polymerase is very difficult to predict. The specification, however, provides no working examples demonstrating (i.e., guidance) enablement for isolated DNA molecule from other gram positive bacteria or gram positive bacteria that are going to be discovered, the isolated DNA molecule comprising a coding region dnaN gene from gram positive bacterium is wherein the DNA molecule encodes

an amino acid sequence comprising SEQ. ID. No. 28, wherein the DNA molecule comprises a nucleotide sequence of SEQ. ID. No. 27 wherein the DNA molecule hybridizes to a nucleic acid molecule of SEQ. ID. NO: 27 under stringent conditions characterized by use of a hybridization buffer comprising 0.9M SSC buffer at a temperature of 37°C, an expression system comprising an expression vector into which is inserted a heterologous DNA molecule from a Gram positive bacterium and an isolated host cell comprising said expression vectors. It is recognized in the art that the function of a protein depends on the sequence of its amino acids in a certain pattern, conformation of the protein due to the amino acid sequence, and the functional properties of the different parts of the protein (see second paragraph in Rudinger J in Peptide Hormones. Editor Parsons JA. Pages 1-7, 1976, University Park Press, Baltimore). Rudinger further add, "The significance of particular amino acids and sequences for different aspects of biological activity can not be predicted *a priori* but must be determined from case to case by painstaking experimental study" (see conclusion on page 6). Therefore change in a nucleotide sequence must be considered highly unpredictable, requiring a specific demonstration of efficacy on a case-by-case basis. The specification provides no disclosure how fragments of dnaN (SEQ.ID.NO: 27) may be used as a target for replication or as a potential drug screening because it fails to provide guidance whether this gene has the ability to interfere in replication either by itself or with DNA polymerases or inactivate or bind to the drug indicating its potential anti-microbial activity. Absent such demonstration, the invention would require undue experimentation to practice as claimed.

Claim Rejections - 35 USC 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Molecular Research Corp. v. CBS, Inc., 793 F2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App.1948)* ("comprising" leaves "the claim open. for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. In *re Gray, 53 F. 2d 520, Il USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948).*

Claims 1and 35-39 are drawn to an isolated DNA molecule from a Gram positive bacterium, the isolated DNA molecule comprising a coding region from (a polC gene, a dnaE gene, a holA gene, a holB gene, a dnaX gene), a dnaN gene, (a ssb gene, a dnaG gene, a dnaB gene), wherein the DNA molecule comprises the coding region from the dnaN gene, wherein the Gram positive bacterium is *Streptococcus pyogenes, wherein* the DNA molecule encodes an amino acid sequence comprising SEQ. ID. NO. 28, wherein the DNA molecule comprises a nucleotide sequence of SEQ. ID. NO. 27, wherein the DNA molecule hybridizes to a nucleic acid molecule of SEQ. ID. NO. 27 under stringent conditions characterized by use of a hybridization buffer comprising 0.9M SSC buffer at a temperature of 37^{o}C.

Claims 55-56 are drawn to an expression system comprising an expression vector into which is inserted a heterologous DNA molecule comprising a coding region from dnaN gene, wherein the heterologous DNA molecule is in sense orientation and correct reading frame .

11. Claims 1, 35-38 and 55-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al U.S.Patent 6,699,703

Doucette-Stamm et al disclose an isolated DNA, SEQ.ID.NO: 1744 dnaN gene from Streptococcus (gram positive, claims 1, 35 and 36) comprising dnaN coding region (see sequence alignment) from position 1, ATG to 1133 which is 71.1 % identical to SEQ.ID.NO: 27. Therefore, this nucleic acid reads on claims 38 and 39 because recitation of "an" is interpreted as less than the full-length nucleic acid. Thus, the prior art reads on claims 1, 35, 36 and 38. Since the polynucleotide starts with the coding region ATG, it encodes an amino acid (less than the full length protein) sequence 4405, which is 72.2% identical to the disclosed sequence (see sequence alignment) and thus read on claim 37. The prior art discloses a cDNA encoding an S. pneumoniae polypeptide can be obtained by isolating total mRNA (column 17 of the patent from an appropriate strain. Double stranded cDNA can then be prepared from the total mRNA. Subsequently, the cDNA can be inserted into a suitable plasmid or viral (e.g., bacteriophage) vector and thus the limitations of claims 55-56 were anticipated by the prior art.

12. Claims 1, and 35 ~~and 36~~ are rejected under 35 U.S.C. 102(b) as being anticipated by Moriya et al 1985, Nucleic acids research, Vol, 13, 2251-2265.

Moriya 1985 disclose an isolated *Bacillus subtilis (*, a gram positive) genome sequence that includes open reading frame ORF378 (coding region). Comparison of amino acid sequence with known protein in E.coli identified ORF 378 as a dnaN gene (figure III, stating at 2141, table 1, line 2, figure 4, ORF378 and page 2263). The prior art DNA sequence reads on the claimed invention, as recitation of "from S.pyogenes" does not distinguish one gene from the other. Further, there are no structural and functional properties between the genes in the claimed invention. Therefore, the prior art DNA reads on the claims 1, and 35 ~~and 36~~. Thus, the prior art anticipated the claimed invention.

13. Claims 1, 35-38 and 55-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Ueyama e t al U.S.Patent 6,245,906.

Ueyama et al disclose an isolated DNA, SEQ.ID.NO: 2 dnaN gene from S.pyogenes (gram positive, claims 1, 35 and 36) comprising dnaN coding region (see sequence alignment) from position 2324, ATG to 3200 which is 74.9% identical to SEQ.ID.NO: 27. Therefore, this nucleic acid reads on claims 38 and 39 because recitation of "an" is interpreted as less than the full-length nucleic acid. Thus, the prior art reads on claims 1, 35, and 36,38. Since the polynucleotide starts with the coding region ATG, it encodes an amino acid (less than the full length protein) sequence MIQFSIN and thus read on claim 37. The prior art discloses that clinical isolate of Streptococcus pyogenes was cultured and genomic DNA was extracted. The extracted DNA was completely digested with restriction enzyme HindIII, then random cloned into vector pGEM-3Z and thus the limitations of claims 55-56 were anticipated by the prior art.

Remarks

15. Claims 1, 35-39 and 55-57 are rejected.

Conclusion

16. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D

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